AUG 3 0 2001

K012322

SYBRON DENTAL SPECIALTIES

Section III - 510(k) Summary of Safety and Effectiveness

Submitter:

Sybron Dental Specialties, Inc.
1717 W. Collins Avenue
Orange, California 92867
(714) 516-7484 - Phone
(714) 516-7488 - Facsimile
Colleen Boswell - Contact Person

Date Summary Prepared: July 2001

Device Name:

- Trade Name – *OptiBond 2*
- Common Name – Pit and Fissure Sealant
- Classification Name – Pit and Fissure Sealant and Conditioner, per 21 CFR § 872.3765

Devices for Which Substantial Equivalence is Claimed:

- Kerr Corporation, *Guardian Seal*

Device Description:

OptiBond 2 is a multi-purpose bonding agent designed to be used in direct situations, i.e., composite to enamel and/or dentin, composite repair, porcelain repair, composite to metal, amalgam sealing, bonding composite core build-up materials, cavity liner, pulp capper, pit and fissure sealant, and indirect situations, i.e., onlays, inlays and crowns.

Intended Use of the Device:

The intended use of *OptiBond 2* is for bonding in direct situations, i.e., composite to enamel and/or dentin, composite repair, porcelain repair, composite to metal, amalgam sealing, bonding composite core build-up materials, cavity liner, pulp capper, pit and fissure sealant, and indirect situations, i.e., onlays, inlays and crowns.

Substantial Equivalence:

OptiBond 2 is substantially equivalent to other legally marketed devices in the United States. The sealant agent marketed by Kerr Corporation functions in a manner similar to and is intended for the same use as the product manufactured by Kerr Dental Materials Center.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 0 2001

Ms. Colleen Boswell
Director, Corporation Compliance
Sybron Dental Specialties, Incorporated
1717 West Collins Avenue
Orange, California 92867

Re: K012322
Trade/Device Name: OptiBond 2
Regulation Number: 872.3200
Regulatory Class: II
Product Code: KLE
Dated: July 18, 2001
Received: July 23, 2001

Dear Ms. Boswell:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K012322

Section I

Indications for Use Statement

Ver/ 3 - 4/24/96

Applicant: Kerr Dental Material Center

510(k) Number (if known): K012322

Device Name: OptiBond 2

Indications For Use:

OptiBond 2 is a multi-purpose bonding agent designed to be used in direct situations, i.e., composite to enamel and/or dentin, composite repair, porcelain repair, composite to metal, amalgam sealing, bonding composite core build-up materials, cavity liner, pulp capper, pit and fissure sealant, and indirect situations, i.e., onlays, inlays and crowns.

(Division Sign-Off) Pamela Scott for Susan Runner
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012322

Prescription Use ✓ **Over-the-Counter Use** _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)
(Optional Format 1-2-96)